UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/502,945	02/11/2000	Matthew J. Scanlan	L0461/7081-(JRV)	5906

7590 11/16/2004

John R. Van Amsterdam
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210

EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/502,945	SCANLAN ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,37-40 and 57-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6, 37-40, 57-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 08/25/04 is acknowledged. Claims 6, 57-61 are amended. Claims 6, 37-40, and 57-67 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

As shown in the last Office action, which claims 57, 59-61, 62, and 63-67, drawn to the non-elected species were included in the examination the search, examination had been expanded to the other species in the claims because the elected species protein encoded by SEQ IS NO:2 was determined to be free of art.

Priority, Granted

Applicant's claim for domestic priority under 35 U.S.C. 120 and /0r 121(e) is acknowledged, and granted.

Claim Objections, Withdrawn

The objection of claim 6 is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112

The rejection of claims 57-61 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of the amendment.

Claim 6, and 57-61 **remain rejected** for reason of record under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6, and 57-61 are interpreted as drawn to genus of proteins encoded by nucleic acid molecules hybridizing to SEQ ID NO:1-5 under the recited conditions.

Applicant argues that based on the election of SEQ ID NO:2 as the species for examination, claims 6, which is a generic claim should be examined with respect to SEQ ID NO:2, not all of SEQ ID NOs 1-5. Thus, the Examiner's comparison of structural relatedness/unrelatedness of the proteins encoded by SEQ ID NOs 1-5 is not relevant to the examination of the claims. SEQ ID NO:2 is disclosed in the specification as filed and is representative of the genus of nuclei acids that encode the claimed proteins. The nucleic acid molecules recited in the claims as encoding the claimed proteins are highly related in structure (nucleotide sequence) to SEQ ID NO:2. A genus of nucleic acid molecules encoding a genus of proteins is not routinely defined in the art by a listing of sequences, chemical formulas or chemical names. Instead, the art routinely identifies nucleic acid molecules by hybridization to a particular nucleotide sequence. Hybridization conditions in combination with a reference sequence provide a precise definition of the claimed hybridizing nucleic acid molecule by physical properties. The function of claimed genus of cancer-associated proteins is the ability to stimulate a specific immune response. Applicants are unclear as why the ability to use SEREX to screen for other, unrelated cancer-associated proteins is relevant to the patentability of the claimed genus of proteins that are encoded by the disclosed SEQ ID

NO:2 and structurally related nucleic acid molecules. These arguments have been fully considered but found unpersuasive for the following reasons.

First, disclosing a species, i.e. SEQ ID NO:2 is not considered to be representative numbers of the claimed genus, which includes allelic variants or homologs, or splicing variants that the instant specification do disclose how the structure(s) looks like.

The base claim 6, and the dependent claims 57-61 (note the proteins of claims 57-61 are encoded by the nucleic acid molecules that are hybridized to SEQ ID NOs 1-5) as currently construed encompasses a genus of proteins with unrelated structures as long as they are cancer antigens that stimulate immune response. The specification teaches instant SEQ ID NO:1-5, all human cDNAs with unrelated structures have been isolated through SEREX method, an immunoscreening technique using a cancer patient's serum containing autoantibodies. The disclosure indicates that the SEQ ID NOs:1-5 encode antigens recognized by an immune system of an autologous host. The specification at pages 9-13 teaches that SEQ ID NOs:1-4 isolated through the SEREX technique are novel gene products, and SEQ ID NO:5 is a splicing variant of SEQ ID NO:4. SEQ ID NOs: 1-4 do not share any structural similarities. Proteins encoded by SEQ ID NO:1-4 do not share common structures but all of them have the same function, i.e. "stimulates an immune response". In other words, there is not structure/function correlation. One cannot expect the recited function by looking at the structure or vice versa. Only way, one could obtain the claimed cancer antigen/protein is to screen. It is

noted that law requires that the disclosure of an application shall inform those skilled in the art how to make and use the alleged discovery, not how to screen it for themselves.

The new matter rejection of claims 6, and 57-61 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in view of the amendment.

Claims 6, and 57-61 **remain rejected** under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for proteins encoded by SEQ ID NOs:1-5, does not reasonably provide enablement for the proteins encoded by hybridizing nucleic acid molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 6, and 57-61 are interpreted as drawn to various proteins encoded by nucleic acid molecules hybridizing to SEQ ID NO:1-5 under the recited conditions.

Applicant argues that closely related proteins to the protein encoded by the instant SEQ ID NO:2 having the biological function of being able to stimulate an immune response are claimed, therefore the full scope of the invention does not require undue experimentation given the high level in the art of screening a nucleic acid given the structure of SEQ ID NO:2. These arguments have been fully considered but not persuasive because law requires that the disclosure of an application shall inform those skilled in the art how to make and use the alleged discovery, not how to screen it for themselves.

Claims 37-40, and 62-67 **remain rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 37, 38-40, and 62-67 are drawn to a composition comprising a plurality of immunogenic peptides derived from the amino acid sequence of at least one protein of proteins encoded by SEQ ID NO:1-5.

Applicant argues that protein encoded by SEQ ID NO:2 is expressed, because without protein expression, no antibodies would have been generated in cancer patients. This concept provides evidence that the peptides bound to and were presented by one or more MHC molecules presented on the surface of cells, in order to provide T cell help for the B cell antibody response. The enablement law does not require a description of every aspect of the claimed invention because it is expected that one of ordinary skill in the art can exercise routine experimentation to make and use the claimed invention. The analysis for identifying MHC binding peptides from a sequence is well known. These arguments have been fully considered but found unpersuasive for the following reason.

As stated before in the previous Office action, the specification at page 14 states that "T cell responses may be elicited by using peptides derived from the proteins which then complex, non-covalently, with MHC molecules, thereby stimulating proliferation of

cytolytic T cells against any such complexes in the subject." However, the specification does teach which fragment or derived peptides claimed in the instant claims can be used to stimulate immune response and binds to one or more MHC molecules presented on the surface of cells, elicit a cytolytic response. It is not clear if (CTLs) could be generated using any fragment of SEQ ID:1-5. The specification does not teach whether a reasonable number of the vast number of claimed peptides could be used for stimulation of immune response in context of MHC molecules as the base claim 37 claims. As stated before in the previous Office action, US Pat. 5,840,839 teach at column 19 that finding a peptide that binds to a MHC molecules and stimulates immune response is not a trivial matter. The '839 patent at column 19, lines 53 to 67 teaches that structure a T cell epitope that stimulates immune response in context of MHC molecules is unpredictable in the current state of art. The '839 patent at columns 19-20, and Table 1 teaches that the various candidate T cell epitopes selected based on theoretical binding motif of one class of MHC molecule, i.e. HLA-A31 do not work when they are experimentally tested as shown in Table 1. This suggests that theoretically selected T cell binding motifs have to be tested experimentally in order to determine whether they are actually T cell epitopes or not.

The specification provides insufficient guidance with regard to theses issues and provides no working examples of a peptide that would work with any MHC molecule. Considering the state of art, the broad scope of claims in respect to the nature of peptide and also to the nature of MHC molecules, it is concluded that that undue experimentation is required to practice the claimed invention. It is noted that law

requires that the disclosure of an application shall inform those skilled in the art how to make the alleged discovery, not how to screen it for themselves.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

LARRY R. HELMS, PH.D
PRIMARY EXAMINER